

§ 558.58

21 CFR Ch. I (4–1–16 Edition)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(vi) 113.5 to 227	2. Laying chickens: For treatment of coccidiosis in moderate outbreaks. 1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed for 2 weeks. Feed continuously from day-old until onset of production; as the sole source of amprolium.	016592
(vii) 113.5 to 227	Bambermycins 1 to 2.	2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(viii) 227	Laying chickens: For treatment of coccidiosis in severe outbreaks..	Feed for 2 weeks	016592

(3) *Turkeys*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(ii) 113.5 to 227	Turkeys: For prevention of coccidiosis.	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) *Pheasants*. It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159	Growing pheasants: For the prevention of coccidiosis caused by <i>Eimeria colchici</i> , <i>E. duodenalis</i> , and <i>E. phasiani</i> .	Feed continuously as sole ration. Use as sole source of amprolium.	016592
(ii) [Reserved]				

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.58 Amprolium and ethopabate.

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. It is used in chicken feed as follows:

Food and Drug Administration, HHS

§ 558.58

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6.	Broiler chickens: As an aid in the prevention of coccidiosis.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens.	016592
(2) Amprolium 113.5 and ethopabate 3.6.	Lincomycin 2 to 4 ...	Broiler chickens: As an aid in the prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens. Lincomycin as provided by No. 054771 in §510.600(c) of this chapter.	054771
(3) Amprolium 113.5 and ethopabate 36.3.	Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur.	Feed continuously as sole ration; as sole source of amprolium. Not for chickens over 16 weeks of age.	016592
(4) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	1. Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis. Bacitracin as bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) of this chapter.	016592
(5) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50 ...	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for improved feed efficiency.	Feed as the sole ration from the time chickens are placed on litter until market weight. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter.	054771
(6) Amprolium 113.5 and ethopabate 3.6.	Bambermycins 1 to 3.	Broiler chickens: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain, improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in §510.600(c) of this chapter.	016592
(7) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 15	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in §510.600(c) of this chapter.	066104
(8) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 5 to 15.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for increased rate of weight gain.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in §510.600(c) of this chapter.	066104
(9) Amprolium 227 and ethopabate 3.6.	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying chickens	016592

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(10) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 days.	054771
(11) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption.	054771

[41 FR 10990, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.58, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.59 Apramycin.

(a) *Approvals*. Type A articles to sponsors identified in § 510.600(c) of this chapter as follows:

(1) 000986 for 75 grams apramycin (as apramycin sulfate) per pound for use as in paragraph (d)(1) of this section.

(2) [Reserved]

(b) [Reserved]

(c) *Related tolerances*. See § 556.52 of this chapter.

(d) *Conditions of use*—(1) *Swine*—(i) *Amount*. 150 grams per ton.

(ii) *Indications for use*. For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of *Escherichia coli*.

(iii) *Limitations*. Use for 14 days. Withdraw 28 days before slaughter.

(2) [Reserved]

[51 FR 9190, Mar. 18, 1986]

§ 558.68 Avilamycin.

(a) *Specifications*. Each pound of Type A medicated article contains 90.7 grams of avilamycin.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for avilamycin medicated feeds must not exceed 90 days from the date of

issuance. VFDs for avilamycin shall not be refilled.

(d) *Related tolerances*. See § 556.68 of this chapter.

(e) *Conditions of use in swine*—(1) *Amount*. Feed at 73 grams avilamycin per ton of Type C medicated feed (80 ppm) as the sole ration for 21 consecutive days. The veterinarian may direct feeding for up to a total of 42 consecutive days, based on the clinical assessment.

(2) *Indications for use*. Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.

[80 FR 61297, Oct. 13, 2015, as amended at 80 FR 76387, Dec. 9, 2015; 81 FR 17609, Mar. 30, 2016]

§ 558.76 Bacitracin methylenedisalicylate.

(a) *Specifications*. (1) Type A medicated articles containing 10, 25, 30, 40, 50, 60, or 75 grams bacitracin methylenedisalicylate per pound.

(2) Type A medicated article containing 50 grams bacitracin methylenedisalicylate per pound.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use of products in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(iii), (e)(1)(v) through (xiii), and (e)(1)(xv) of this section.